

## **Board of Pharmacy**

### **Initial Statement of Reasons**

Subject Matter of Proposed Regulation: Notice to Consumers

Section Affected: 1707.2

#### Problem Addressed

Recent studies have highlighted the high number of medication errors and their adverse health consequences. The most notable of these studies is To Err Is Human published in 1999 by the Institute of Medicine. This study comprehensively examines the literature on patient safety and makes numerous policy recommendations.

One of the recommendations to prevent errors and improve patient outcomes is to involve patients whenever possible as part of the health care team, and specifically to improve patients' knowledge about their treatment including drug therapy. This requires that patients make known their preferences about health care and drug therapy as well as learn about their conditions and the kinds of medications they are receiving. Specifically, patients should understand what medications they are taking, the doses and times the medication needs to be taken, how long to take the medications, precautions about interactions with alternative therapies or with alcohol, possible side effects, and any activities that should be avoided such as driving or the use of machinery.

#### Specific Purpose of the Regulation

This proposed regulation would modify existing requirements in section 1707.2(f) regarding a required notice that pharmacies must either post in the premises or provide on a written receipt. The board believes that a key service provided by pharmacists is patient education and consultation. Since 1992, the board has required pharmacists to consult patients on all new prescription medications, and for even longer has required pharmacists to respond to any patient inquiries on any medication or when the pharmacist believes it is necessary. However, many patients still do not understand or fully understand how to take their medications appropriately and the health impact and costs are staggering.

To this end, the board wants to assure patients have answers to the questions that will aid them in complying with drug treatment regimens, and relevant warnings drug therapy is proceeding (or not proceeding) as it should. The board proposes to place this information on a poster which must be displayed in the pharmacy within patients' view (or alternatively printed on a receipt). The poster will contain general information about prescription drugs and will list five questions patients need the answers to so that they may receive optimal drug therapy. This will aid pharmacist-to-patient consultation and education, and aid patients in more thorough understanding about how to take their medications appropriately. By placing the questions in the pharmacy, they will be readily accessible to patients at the time they need the questions.

Generic drugs are proven to be a low cost alternative to brand-name drug therapy. The board believes that patients understand the concept of generic drugs, but in interests to aid patients in reducing expenses, especially now that drug manufacturers market brand-name drugs directly to patients, a reminder that generic drugs can save patients money is important. And to many patients,

the cost of a prescription drug is very important in determining where medication is purchased; hence the board wishes to assure patients know they can obtain a price quote for a drug either in person or via telephone.

The key information the board wishes to stress to patients is to talk to your pharmacist, understand your drug therapy, you have a right to price quotations for a medication before it is dispensed and use of generics can lower your expenses for prescription drugs. This is in keeping with the board's consumer protection mandate – one of the most effective ways to protect consumers is to educate them so that they may represent themselves in the marketplace. Patients and pharmacists can discuss the availability of additional pharmacy services – but on a poster, where space is at a premium, the board wants to assure the most important information is available for ready access by the patient.

Pharmacies will be free to add additional items to the notice when printed on a receipt, as this will be the minimal information the board will require to be distributed on receipts. And in those pharmacies that will display a poster and not print this information on the back of a receipt, additional information about pharmacy services especially concerning drug benefit coverage is typically posted in and around pharmacies.

### Factual Basis

The following are among the statistics cited by the Institute of Medicine and the National Council on Patient Information and Education to establish the unacceptably high number of deaths and injuries that result from medical errors.

- Medication errors are estimated to kill more than 7,000 patients per year nationwide.
- Between 1983 and 1993 there was an 8 fold increase in deaths attributable to medication errors, compared to a 2 fold increase in hospital deaths in the United States.
- The cost of hospital-related medication errors alone exceeds \$2 billion per year. Hospital patients account for a fraction of all prescriptions filled each year.
- Approximately 48 percent of the prescription drugs on the market today have become available only since 1990.
- Medications are the most frequent medical intervention, with an average of 11 prescriptions prescribed per person in the United States.
- One study found that 4.2 percent of outpatient prescriptions result in adverse drug reactions. By 2004, 3 billion outpatients prescriptions are projected to be filled.

These statistics (assuming 10% of all prescriptions are written in California) indicate that over 12,600,000 adverse drug reactions could occur each year in California on an outpatient basis alone. A great many of these reactions are preventable medication errors and inflict pain, loss of function and economic loss on consumers.

The board believes there is no acceptable incidence of medication errors in a pharmacy. Any error needs to be thoroughly evaluated to prevent its recurrence. For the last several years, the board has pursued and implemented requirements that pharmacies establish quality assurance

programs to evaluate medication errors and make corresponding improvements in pharmacy operations.

Yet another way to impact and prevent patient errors is patient education, and increased patient involvement in their own drug therapy. The way to achieve this is by educating patients about the information they need to ask to understand their drug therapy.

According to Preventing Medication Errors: Strategies for Pharmacists, authored by the Joint Commission on Accreditation of Healthcare Organizations and published in 2001, the pharmacist is often the last health care provider the patients speaks with before taking medication, which provides pharmacists with “an excellent opportunity to tie all the pieces together for the patient.” (p.36) And that simply conveying information is not patient education, which instead needs more active engagement of the patient and will more likely result in behavior change.

### Underlying Data

In determining what information needed to be changed on its “Notice to Consumers,” the board relied heavily on quality assurance models in healthcare institutions and the substantial literature available on quality improvement, all of which include components on engaging and educating patients about their drug therapy as a strategy to reduce errors and improve patient outcomes. The Institute of Medicine recommends five questions patients should understand before taking medications. The National Council on Patient Information and Education recommends at least seven questions. The Board of Pharmacy for years has published a flyer with four questions patients should understand. Questions from all these sources focus on similar information, which the board has blended into five questions patients should understand before they take any medication. These questions, as they may be amended through the public comment period required of this rulemaking, will be incorporated into the “Notice to Consumers” to aid patients in learning more about their drug therapy.

As an example of patients not understanding their drug therapy, according to the National Council on Patient Information and Education, one of the most common examples of patients not following their prescription regimen involves antibiotic therapy, unusually when patients stop taking their medicine prematurely. This can cause a recurrence of the condition that the antibiotics were originally prescribed to treat.

According to the National Council on Patient Information and Education:

- Adverse drug reactions (ADRs) may be the 4<sup>th</sup> - 6<sup>th</sup> leading cause of death in the U.S.: researchers found that in 1994, over 2.2 million hospitalized patients had serious ADRs, and 106,000 patients had fatal ADRs. Serious ADRs occurred in 6.7 percent of hospitalized patients.
- In 1999, the average price of a brand-name prescription was \$61.33 versus \$18.45 for a generic prescription.
- In 2000, the number of outpatient prescriptions is expected to reach 3 billion versus 2.7 billion in 1999. By 2004, this is expected to reach 4 billion.
- In 1998, nearly two-thirds of physician office visits ended with a prescription being written, making medication therapy the most commonly mentioned therapeutic service.

- In 1998, of the office visits involving medication therapy, 36.5 percent of patients received two or more prescriptions; over 10 percent received four or more prescriptions.
- Through 2010, the fastest-growing age cohort will be those aged 45-64. After 2010, those aged 65 and older will be the fastest-growing cohort.
- The elderly (aged 65 and older) account for 13 percent of the U.S. population, but account for 34 percent of all prescription medicines dispensed and 42 percent of outpatient prescription expenditures.
- The average number of prescriptions per elderly person is projected to be 28.5 in 2000, and is projected to reach 38.5 prescriptions by 2010.
- As many as 40 percent of cancer patients are taking unconventional therapies, but don't tell their physicians unless specifically asked. Examples of such therapies included St. John's wort, shark cartilage, and mega doses of vitamins.
- As much as 50 percent of medications prescribed for chronic use never get taken.

In Medication Errors, Causes, Prevention and Risk Management, edited by Michael R. Cohen, and published in 2000, the benefits of patients asking questions of pharmacists is encouraged:

Patients can do a great deal to decrease the probability that they will experience a medication error. To do so, they need not spend hours researching medications and diseases. Nor do they have to know everything about the drugs they are taking. They simply need to know what to ask and to insist on answers. An informed patient is one of the best safeguards against medication errors. (p14.1)

Placement of such information in a pharmacy, where it is readily visible to patients when they obtain their medications, offers a tremendous opportunity to provide patients with this information at a time when they will most need it.

### Business Impact

This regulation will require pharmacies to post a revised notice to consumers poster or alternatively, alter the information that some pharmacies may print on the back of a receipt. No new requirement is being mandated in this rulemaking. The board will print and distribute the posters to pharmacies, as it has done for years.

### Specific Technologies or Equipment

The proposed revision to section 1707.2 does not mandate the use of specific technologies or equipment. However, the proposed regulation requires the display of an updated "Notice to Consumers" or alternatively, provision of the updated information on a written receipt.

The current regulation already requires posting of the notice in the pharmacy or provision of the information on a written receipt. In this rulemaking the content of the message is being changed and updated from the version that was adopted in the early 1980s, when the health care profession and patient care were substantially different.

The board will produce a professionally designed (and more visually attractive) poster containing the updated notice and distribute this poster to all pharmacies licensed in California. Pharmacies

not wishing to display the poster in the pharmacy may alternatively provide the information on a written receipt.

The board will use a portion of its publication budget to design, print and distribute these posters to pharmacies, and will make the poster available in additional languages in future years as its budget permits. This is a strategic objective of the board.

The board will also obtain an 800 number for consumers to contact the Board of Pharmacy with inquiries, and include this number on the poster. The costs for this toll-free number are expected to be \$14,000 annually.

#### Consideration of Alternatives

The board has not identified any equally effective alternatives that would lessen any adverse impact on business. Patients need information about prescription drug therapy when they are obtaining prescription medications. Placing this information in the pharmacy where it will be available at the time patients need/want the information is a highly effective way to get this information to patients at the time they need the information prove patient knowledge.

The revised Notice to Consumers poster will replace the poster currently available from the board, and the board will continue to make the poster available to pharmacies without a fee. Some pharmacies may not wish to display a poster in the pharmacy, and in these pharmacies the required information needs to be printed on the back of the receipt.